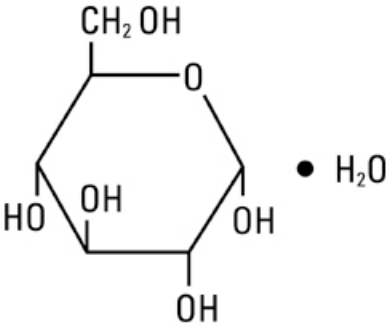
DEXTROSE - dextrose monohydrate injection, solution
Hospira, Inc.

Concentrated source of carbohydrate calories for intravenous infusion.
NOTE: These solutions are hypertonic– see WARNINGS and PRECAUTIONS.
Partial-Fill Flexible Plastic Containers
R_x only

DESCRIPTION

20%, 30%, 40%, 50% and 70% Dextrose Injection, USP (concentrated dextrose in water) is a sterile, nonpyrogenic, hypertonic solution of Dextrose, USP in water for injection for intravenous administration after appropriate admixture or dilution.
Partial-fill containers, designed to facilitate admixture or dilution to provide dextrose in various concentrations, are available in various sizes. See table under HOW SUPPLIED for summary of content and characteristics of these concentrated solutions.
The solutions contain no bacteriostat, antimicrobial agent or added buffer and are intended only for use as a single-dose injection following admixture or dilution.
The flexible plastic container is fabricated from a specially formulated polyvinylchloride. Water can permeate from inside the container into the overwrap but not in amounts sufficient to affect the solution significantly. Solutions in contact with the plastic container may leach out certain chemical components from the plastic in very small amounts; however, biological testing was supportive of the safety of the plastic container materials.
Exposure to temperatures above 25°C/77°F during transport and storage will lead to minor losses in moisture content. Higher temperatures lead to greater losses. It is unlikely that these minor losses will lead to clinically significant changes within the expiration period.
Dextrose Injection, USP is a parenteral fluid and nutrient replenisher.
Dextrose, USP is chemically designated D-glucose, monohydrate ($C_6H_{12}O_6 \cdot H_2O$), a hexose sugar freely soluble in water. It has the following structural formula:



Water for Injection, USP is chemically designated H_2O.

CLINICAL PHARMACOLOGY

When administered intravenously, solutions containing carbohydrate in the form of dextrose restore blood glucose levels and provide calories. Carbohydrate in the form of dextrose may aid in minimizing liver glycogen depletion and exerts a protein sparing action.
Dextrose injection undergoes oxidation to carbon dioxide and water.
Water is an essential constituent of all body tissues and accounts for approximately 70% of total body weight. Average normal adult daily requirement ranges from two to three liters (1.0 to 1.5 liters each for insensible water loss by perspiration and urine production, respectively).
Water balance is maintained by various regulatory mechanisms. Water distribution depends primarily on the concentration of electrolytes in the body compartments, and sodium (Na^+) plays a major role in maintaining physiologic equilibrium.

INDICATIONS AND USAGE

20%, 30%, 40%, 50% and 70% Dextrose Injection, USP (concentrated dextrose in water) in partial-fill containers is indicated for admixture with amino acids or dilution with other compatible I.V. fluids to provide variable final dextrose concentrations for intravenous infusion in patients whose condition requires parenteral nutrition.

CONTRAINDICATIONS

A concentrated dextrose solution should not be used when intracranial or intraspinal hemorrhage is present nor in the presence of delirium tremens if the patient is already dehydrated.
Dextrose injection without electrolytes should not be administered simultaneously with blood through the same infusion set because of the possibility that pseudoagglutination of red cells may occur.

WARNINGS

Concentrated dextrose in water should be administered only after suitable dilution. Hypertonic dextrose solutions should be given slowly. Significant hyperglycemia and possible hyperosmolar syndrome may result from too rapid administration. The physician should be aware of the symptoms of hyperosmolar syndrome, such as mental confusion and loss of consciousness, especially in patients with chronic uremia and those with known carbohydrate intolerance.

The intravenous administration of these solutions can cause fluid and/or solute overloading resulting in dilution of serum electrolyte concentrations, overhydration, congested states or pulmonary edema.

WARNING: This product contains aluminum that may be toxic. Aluminum may reach toxic levels with prolonged parenteral administration if kidney function is impaired. Premature neonates are particularly at risk because their kidneys are immature, and they require large amounts of calcium and phosphate solutions, which contain aluminum.

Research indicates that patients with impaired kidney function, including premature neonates, who receive parenteral levels of aluminum at greater than 4 to 5 mcg/kg/day accumulate aluminum at levels associated with central nervous system and bone toxicity. Tissue loading may occur at even lower rates of administration.

FOR PERIPHERAL VEIN ADMINISTRATION

Hypertonic dextrose solutions (above 5% concentration) should be given slowly, preferably through a small bore needle into a large vein, to minimize venous irritation.

FOR CENTRAL VENOUS ADMINISTRATION

Concentrated dextrose should be administered via central vein after appropriate admixture or dilution when required.

PRECAUTIONS

Electrolyte deficits, particularly in serum potassium and phosphate, may occur during prolonged use of concentrated dextrose solutions. Blood electrolyte monitoring is essential, and fluid and electrolyte imbalances should be corrected. Essential vitamins and minerals also should be provided as needed.

To minimize hyperglycemia and consequent glycosuria, it is desirable to monitor blood and urine glucose and if necessary, add insulin. When concentrated dextrose infusion is abruptly withdrawn, it is advisable to follow with the administration of 5% or 10% dextrose to avoid rebound hypoglycemia.

Solutions containing dextrose should be used with caution in patients with known subclinical or overt diabetes mellitus.

Care should be exercised to insure that the needle (or catheter) is well within the lumen of the vein and that extravasation does not occur.

Concentrated dextrose solutions should not be administered subcutaneously or intramuscularly.

Do not administer unless solution is clear and container is undamaged. Discard unused portion.

Pregnancy Category C.

Animal reproduction studies have not been conducted with dextrose. It is also not known whether dextrose can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Dextrose should be given to a pregnant woman only if clearly needed.

Pediatric Use:

The safety and effectiveness in the pediatric population are based on the similarity of the clinical conditions of the pediatric and adult populations. In neonates or very small infants the volume of fluid may affect fluid and electrolyte balance.

Frequent monitoring of serum glucose concentrations is required when dextrose is prescribed to pediatric patients, particularly neonates and low birth weight infants.

In very low birth weight infants, excessive or rapid administration of dextrose injection may result in increased serum osmolality and possible intracerebral hemorrhage.

This product contains no more than 25 mcg/L of aluminum.

ADVERSE REACTIONS

Hyperosmolar syndrome, resulting from excessively rapid administration of concentrated dextrose may cause hypovolemia, dehydration, mental confusion and/or loss of consciousness.

Reactions which may occur because of the solution or the technique of administration include febrile response, infection at the site of injection, venous thrombosis or phlebitis extending from the site of injection, extravasation and hypervolemia.

If an adverse reaction does occur, discontinue the infusion, evaluate the patient, institute appropriate therapeutic countermeasures and save the remainder of the fluid for examination if deemed necessary.

OVERDOSAGE

In the event of overhydration or solute overload during therapy, reevaluate the patient and institute appropriate corrective measures. See WARNINGS and PRECAUTIONS.

DOSAGE AND ADMINISTRATION

Concentrated Dextrose in Water is administered by slow intravenous infusion (a) After admixture with amino acid solutions or (b) After dilution with other compatible I.V. fluids. Dosage should be adjusted to meet the requirements of each individual patient.
The maximum rate at which dextrose can be infused without producing glycosuria is 0.5 g/kg of body weight /hr. About 95% of the dextrose is retained when infused at a rate of 0.8 g/kg/hr.
As reported in the literature, the dosage and constant infusion rate of intravenous dextrose must be selected with caution in pediatric patients, particularly neonates and low birth weight infants, because of the increased risk of hyperglycemia/hypoglycemia.
Clinical evaluation and periodic laboratory determinations are necessary to monitor changes in fluid balance, electrolyte concentrations, and acid-base balance during prolonged parenteral therapy or whenever the condition of the patient warrants such evaluation.
A list of nutritional admixture values is appended.
Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit. See PRECAUTIONS.

Drug Interaction

Additives may be incompatible. Consult with pharmacist, if available. When introducing additives, use aseptic technique, mix thoroughly and do not store.
Some opacity of the plastic due to moisture absorption during sterilization process may be observed. This is normal and does not affect the solution quality or safety. The opacity will diminish gradually.

WARNING: Do not use flexible container in series connections.

HOW SUPPLIED

20%, 30%, 40%, 50% or 70% Dextrose Injection, USP are supplied in single-dose partial-fill flexible containers. See the following table.

Concentrated Dextrose In Water
Content and Characteristics

List No.	% Conc.	Fill Volume (mL)	Total Grams of Dextrose Hydrous Per Container	kcal*/100 mL (per Container)	mOsmol/liter (calc.)	pH (range)
7935	20	500	100	68 (340)	1009	4.3 (3.2 - 6.5)
8004	30	500	150	102 (510)	1514	4.3 (3.2 - 6.5)
7937	40	500	200	136 (680)	2018	4.3 (3.2 - 6.5)
7936	50	500	250	170 (850)	2523	4.3 (3.2 - 6.5)
7918	70	500	350	238 (1190)	3532	4.3 (3.2 - 6.5)
7936	50	1000	500	170 (1700)	2523	4.3 (3.2 - 6.5)

*Caloric value calculated on the basis of 3.4 kcal/g of dextrose, hydrous.

Nutritional Admixture Values

500 mL of Concentrated Dextrose mixed with 500 mL Aminosyn®7% or
1000 mL of Concentrated Dextrose mixed with 1000 mL of Aminosyn 7%

Dextrose Pre-Dilution Concentration	Admixture Non-Protein kcal/g N	Admixture Non-Protein kcal/liter	Admixture g N/liter	Admixture Dextrose Concentration
20%	62	340	5.5	10%
30%	93	510	5.5	15%

40%	124	680	5.5	20%
50%	155	850	5.5	25%
70%	216	1190	5.5	35%

Store at 20 to 25°C (68 to 77°F). [See USP Controlled Room Temperature.] Protect from freezing.
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